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FINAL REPORT OF A MISSION

CARRIED OUT IN

UKRAINE

FROM 06 TO 10 DECEMBER 2010

IN ORDER TO EVALUATE THE ANIMAL HEALTH CONTROLS IN PLACE FOR POULTRY MEAT, EGGS AND THEIR PRODUCTS FOR POTENTIAL EXPORT TO THE EUROPEAN UNION

Executive Summary

The report describes the outcome of an inspection carried out by the Food and Veterinary Office (FVO) in Ukraine from 6 to 10 December 2010.

Ukraine has applied to be included on the lists of third countries laid down in Commission Regulation (EC) No 798/2008, from which imports into the European Union (EU) of poultry meat, eggs and egg products are authorised, and in Commission Decision 2007/777/EC, from which imports into the EU of poultry meat products are authorized. Accordingly, the objectives of the inspection were:

- *to assess the performance of the competent authorities (CA) of Ukraine with regards to the implementation of national legislation for prevention and control of highly pathogenic avian influenza (HPAI) and Newcastle disease (ND);*
- *to evaluate whether the assurances provided by the CA are in compliance with or equivalent to the relevant EU animal health requirements; and*
- *to evaluate veterinary certification conditions in place for the relevant commodities in order to verify that they are in conformity with or at least equivalent to EU requirements.*

Overall, the report concludes that a sufficiently empowered and well resourced CA is able to carry out effective animal health controls on the poultry population in Ukraine and can largely ensure detection and adequate management of an outbreak of HPAI. Besides that, the vaccination policy against ND can be considered equivalent to EU provisions in that respect. Therefore, in general, the CA are in a position to offer the animal health guarantees required for certifying poultry meat, eggs and their products to be exported to the EU, in particular because of the limited number of fully integrated companies that are envisaged to avail of this possibility.

Nonetheless, some shortcomings have been identified that undermine the capability of the system in place to manage certain risks to the general animal health situation of the poultry population in Ukraine. These concern in particular:

- *Legal requirements in place on the definitions of AI and ND, as well as on the distinction between low pathogenic avian influenza (LPAI) and HPAI, that can not be considered fully in accordance with EU provisions and international standards laid down by the World Organisation for Animal Health (hereafter, OIE) in the Terrestrial Animal Health Code (hereafter referred to as the Terrestrial Code);*
- *Import risk management measures for poultry commodities that are not totally in compliance with standards laid down in the Terrestrial Code and that can not be considered fully equivalent to EU provisions;*
- *Virological and serological diagnostic systems for AI and ND that are not effective enough to guarantee confirmation of outbreaks of these diseases without unnecessary delay and to unequivocally exclude the possible circulation of strains of LPAI and field strains of ND; and*
- *Implementation of the sero-surveillance programme for AI in backyard flocks and wild birds that can not be considered sensitive enough to detect low or inapparent incidence of the disease in those bird populations.*

The CA undertook to take immediate action to address the above mentioned shortcomings and already offered evidence in that respect during the closing meeting.

The report addresses a number of recommendations to the Ukrainian CA aimed at rectifying identified shortcomings and enhancing the control systems in place.

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Abbreviations and definitions used in this report

Abbreviation	Explanation
AI	Avian influenza
CA	Competent authorities
CCA	Central Competent Authority
DVO	District Veterinary Office
ELISA	Enzyme-linked immunosorbent assay
EU	European Union
FVO	Food and Veterinary Office
HA	Haemagglutination test
HI	Haemagglutination inhibition test
HPAI	Highly pathogenic avian influenza
LPAI	Low pathogenic avian influenza
LVS	Local Veterinary Stations
MS	Member States of the European Union
ND	Newcastle disease
NRL	National reference laboratory
OIE	World Organisation for Animal Health
OV	Official veterinarian
PCR	Polymerase chain reaction
RVL	Regional veterinary laboratory
RVS	Regional Veterinary Services
SCVMU	State Committee of Veterinary Medicine of Ukraine
Synanthropic birds	Wild birds with a life cycle adapted to conditions created or modified by human activity
Terrestrial Code	Terrestrial Animal Health Code of the OIE
Terrestrial Manual	Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the OIE

1 Introduction

This inspection took place in Ukraine from 6 to 10 December 2010 as part of the FVO's planned inspection programme and was carried out by two inspectors from the FVO. Representatives from the central competent authority (CCA), the State Committee of Veterinary Medicine of Ukraine (SCVMU), accompanied the FVO team during the inspection.

An opening meeting was held on 6 December 2010 with the representatives of the CCA and other relevant CA, from central and regional levels. At this meeting the FVO team confirmed the scope of, and itinerary for the inspection and received additional information from the representatives of the CA.

2 Objectives Of The Inspection

The objectives of the inspection were:

- to assess the performance of the CA of Ukraine with regards to the implementation of national legislation for prevention and control of HPAI and ND;
- to evaluate whether the assurances the CA can provide regarding the animal health conditions relevant for imports of poultry meat, eggs and their products into the EU, are in compliance with or equivalent to the relevant EU animal health requirements; and
- to evaluate veterinary certification conditions in place for the relevant commodities in order to verify that they are in conformity with or at least equivalent to EU requirements.

In pursuit of the objective, the following sites were visited:

MEETINGS/VISITS		n	COMMENTS
COMPETENT AUTHORITIES	Central	3	Opening and final meetings with representatives of the SCVMU and the other relevant CA. A separate meeting was held with representatives of the CA responsible for official controls related to production and use of vaccines against avian diseases
	Regional	2	Meetings with staff from two regional offices
	District	3	Meetings with staff from three district offices
LABORATORIES		2	National reference laboratory for avian diseases and one regional veterinary laboratory
FARMS		2	One poultry farm with laying hens and one parent flock part of a fully integrated broiler production company

3 Legal Basis for the Inspection

The inspection was carried out under the general provisions of EU legislation, in particular:

- Article 46 of Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules; and
- Article 8 of Council Directive 2002/99/EC on animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption.

Legal acts quoted in this report are listed in Annex I and refer, where applicable, to the latest amended version.

4 BACKGROUND

Commission Regulation (EC) No 798/2008 lays down a list of third countries, territories, zones or compartments from which Member States (MS) shall authorise imports of poultry and poultry products. Moreover, the said Regulation states that those imports should meet conditions equivalent to those applied within the EU and which are in line with requirements for international trade in poultry and poultry products laid down by the standards of the OIE laid down in the Terrestrial Code and in the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (hereafter, Terrestrial Manual).

Commission Decision 2007/777/EC lays down animal health rules for imports of, amongst other commodities, certain meat products for human consumption, including those of poultry origin. Those rules include the lists of third countries and parts thereof from which such imports shall be authorised.

Ukraine has applied to be included on the above mentioned lists of third countries from which imports of poultry meat, eggs and their products into the EU are authorized and has submitted a completed pre-listing questionnaire, as required in these cases, to the Commission services. The information contained therein has been preliminarily evaluated as satisfactory concerning the animal health guarantees that need to be provided by the certifying CA. In addition, two FVO inspections have already been carried out in 2009 and 2010 in order to evaluate food safety issues within the scope of the above mentioned authorisation request. The results of those inspections are described in reports DG(SANCO)/2009-8334 – MR Final and DG(SANCO)/2010-8755 – MR Final, which, together with the responses of the CA to the reports' recommendations, are accessible at the following Website:

http://ec.europa.eu/food/fvo/ir_search_en.cfm

The poultry industry in Ukraine is well developed and it includes several high throughput fully integrated broiler companies, including slaughterhouses and processing plants, and some integrated companies producing table eggs. Several species of poultry including chicken, laying hens, turkeys, ducks, geese, quails and to a lesser extent guinea fowl and a few ratites are reared commercially. There are some 150 million poultry in the commercial sector and more than 50 million kept in small non-commercial and backyard flocks.

According to the CA, a very limited number of fully integrated companies with a closed internal cycle, i.e. from the grandparent flocks to broiler production, and also including their own slaughterhouses and processing plants, would avail of the possibility to export poultry meat or meat products to the EU. Besides that, at the time of this visit, the only company planning to export egg products to the EU would do so on the basis of raw material imported exclusively from MS.

5 FINDINGS AND CONCLUSIONS

5.1 LEGISLATION AND COMPETENT AUTHORITIES PERFORMANCE

5.1.1 Legal requirements

The EU legal requirements regarding animal health measures and certification conditions applicable to the scope of the inspection are set out in Directive 2002/99/EC, Regulation (EC) No 798/2008 and Decision 2007/777/EC.

Imports of poultry meat and eggs from third countries are only allowed if the CA offers animal health guarantees equivalent to those described in Chapter I of Directive 2002/99/EC. When drawing up or updating lists of third countries eligible to export to the EU, particular account of the

following aspects of CA performance must be taken into consideration:

- the legislation of the third country;
- the organisation of the competent veterinary authority and its inspection services in the third country;
- the powers of these services;
- the supervision to which they are subject;
- the means at their disposal, including staff capacity, to apply their legislation effectively.

Regulation (EC) No 798/2008 establishes a list of third countries, territories, zones and compartments from which MS shall authorize imports of poultry and poultry products. This Regulation also lays down the animal and public health veterinary certification requirements for the importation into the EU of the said commodities.

Decision 2007/777/EC lays down animal health rules for imports of, amongst other commodities, certain meat products for human consumption, including those of poultry origin, and includes the model animal health certificates and rules on the origin and treatments required for those imports.

5.1.2 Findings

Ukraine has an extensive body of national legislation covering the various aspects of prevention, control and eradication of poultry diseases, in particular as regards AI and ND. This legislation empowers the CA to:

- take measures to be applied in the event of outbreaks of notifiable diseases, in particular AI and ND;
- set up arrangements with respect to implementation of annual monitoring and surveillance programmes for those diseases;
- impose approval conditions to be fulfilled by commercial poultry farms;
- supervise animal health conditions in small non-commercial and backyard flocks keeping poultry;
- verify bio-security measures to be applied by the commercial poultry industry; and
- organise and implement compulsory vaccination plans, including one for ND.

However, some weaknesses prevent this legislation from being considered fully equivalent to EU requirements and international standards laid down in the OIE Terrestrial Code and Manual, in particular:

- Current definitions for ND and AI, as well as the distinction between LPAI and HPAI are not fully in line with international standards and, consequently, they do not guarantee at the moment that LPAI would be detected and notified, and do not cover adequate bio-molecular definitions for HPAI and potentially virulent ND virus strains;
- Current legal requirements are not sufficiently clear in relation to the authorisation system for ND live attenuated vaccines and, consequently, they can not unequivocally ensure that the alleged prohibition to use master seed strains other than those of a lentogenic type is actually in force and that rules declared to be also applicable on tests to be carried out on each batch of an authorised vaccine, need to be always complied with in practice;
- The legal framework establishing a system of import requirements for all commodities that bear a risk of introducing AI or ND does not offer equivalent guarantees to the import risk management system in the EU. This is mainly due to the limited scope of the health attestations required by current import certificates whereby exporting countries do not

always have to certify the health and vaccination status of the poultry populations from which the commodities are sourced with respect to AI and, in particular, ND.

Within the structure of the SCVMU there is a clear chain of command from the departments at central level down to lower levels in the organisation, i.e. the regional veterinary services (RVS) and the district veterinary offices (DVOs).

There is extensive documentation on official controls in this area that includes numerous instructions, guidelines, check-lists and reporting formats; this enables the regular verification of the activities performed by the different levels of the CCA by managerial staff and internal and external audit and inspection systems.

5.1.3 Conclusions

There is extensive national legislation in place covering the most relevant aspects of prevention, control and eradication of poultry diseases, in particular as regards AI and ND; however, some gaps have been identified that prevent it from being considered fully equivalent to EU requirements and international standards laid down in the OIE Terrestrial Code and Manual.

The CA have the competencies, powers and resources to organise and implement animal health controls on the poultry populations of Ukraine, including in case of outbreaks of notifiable diseases. Effectiveness of these controls and the reliability of their outcome in relation to the guarantees to be provided in the framework of the intended exports of products of animal origin to the EU is also supported by extensive documentary evidence of their realisation, and a mostly adequate supervision of their performance.

5.2 LABORATORIES

5.2.1 Legal requirements

Article 46(1)(d) of Regulation (EC) No 882/2004 allows for the Commission to evaluate the resources of the CA. Article 8(1)(h) of Council Directive 2002/99/EC establishes that when drawing up lists of exporting third countries, account shall taken to the regularity, speed and accuracy with which the third country supply information on the existence of infectious or contagious animal diseases.

Point 3 (b) of Article 3.2.6 of the Terrestrial Code requires that official governmental diagnostic laboratories should be subject to strict quality assurance procedures and should use international quality assurance programmes (wherever available) for standardising test methodologies and testing proficiency.

Commission Decision 2006/437/EC approves the diagnostic manual for AI to be applied by MS.

Annex III to Council Directive 92/66/EC lays down procedures for the confirmation and differential diagnosis of ND.

Chapters 2.3.4 and 2.3.14 of the Terrestrial Manual lay down international standards for the diagnosis of AI and ND, respectively.

5.2.2 Findings

The State Scientific and Research Institute for Laboratory Diagnostic and Veterinary and Sanitary Expertise, which is directly accountable to the SCVMU, acts as national reference laboratory (NRL) for both AI and ND.

The FVO team found that:

- Material from suspected cases of ND and AI is analysed in the NRL or one of the regional veterinary laboratories (RVL); techniques used follow the classical diagnostic pathway described in Decision 2006/437/EC and include:
    - virus isolation in embryonated eggs, aimed at ensuring early detection of an AI or ND virus in case of high viral presence or a virulent strain;
    - posterior tests for detecting the AI virus subtype (H5 or H7) are performed by the NRL using haemagglutination inhibition (HI) and should contribute to the preliminary identification of an AI outbreak;
    - additional tests can be performed such as an intravenous pathogenicity index test in six-week-old chickens to detect the presence of HPAI;
    - nucleotide sequencing of the haemagglutinin gene and further typing and characterisation of the isolates would rely on external laboratories from the EU.
- There is a system in place in many commercial farms whereby a number of (sick or weaker) birds are examined for the presence of AI and ND by RVL using virus isolation, but only exceptionally additional tests such as HI or PCR are carried out by the NRL. According to staff of the RVL visited met, they have not found any suspicious case of either disease for many years.
- Use of polymerase chain reaction (PCR) detection for AI by the NRL, despite being ISO 17025 accredited, seems to lack sufficient sensitivity to detect the presence of many H5 and H7 strains as demonstrated by the unsatisfactory results obtained in an international proficiency testing organised by the NRL of a MS. The use of non-validated primers appears to be undermining the diagnostic reliability of the system in place, which adds on to the lower sensitivity of the detection in embryonated eggs. In addition, at the moment PCR is used as the only diagnostic technique for the surveillance of AI in wild birds. No PCR technique is used to exclude the presence of strains of ND in the vaccinated population other than the ones contained in the vaccines authorised or to check swab samples or pathological material from healthy or sick poultry.
- Serological tests are used during monitoring and surveillance of ND (verification of levels of herd immunity) and AI in domestic poultry. The techniques used are haemagglutination (HA), mainly, and ELISA (a commercial kit is used). Details on the validation of these techniques could not be provided and their diagnostic sensitivity has not been sufficiently challenged with the use of international reference sera as only the controls provided by the commercial kits are used. All samples analysed from domestic poultry have been negative, and only antibodies against two type A influenza viruses have been found in the wild bird samples collected since 2008 (of an H5 strain considered LPAI). Therefore, reliability of the results obtained remains limited in the absence of systematic validation of the serological tests and the above mentioned lack of kit-independent controls.
- The NRL has organised national proficiency tests for the HA carried out by RVL. However, only one has been performed for AI (2008) and sera employed were again prepared with the same control sera supplied with the commercial kits. Results checked by the FVO team showed satisfactory outcomes for all these tests.

5.2.3 Conclusions

The CA have set up a laboratory infrastructure that should be capable of detecting the presence of HPAI or ND, but the lack of adequate and reliable molecular techniques to be applied for detection and characterisation of AI and ND virus would undermine:

- the prompt processing of samples from clinical specimens from infected birds in order to confirm a HPAI or ND outbreak without delay; and
- the sensitivity of molecular testing carried out on routine samples from wild birds.

In addition, limited information on the validation and diagnostic sensitivity of the serological tests used casts doubts on the reliability of the results and effectiveness of the AI sero-surveillance campaigns carried out on the domestic birds populations.

5.3 Animal health controls on poultry diseases

5.3.1 Legal requirements

Article 3 of Regulation (EC) No 798/2008 establishes that the commodities shall only be imported into the EU from third countries, territories, zones or compartments listed in columns 1 and 3 of the table in Part 1 of Annex I to the said Regulation.

Article 7 of Directive 2002/99/EC requires that products of animal origin intended for human consumption that are introduced from third countries must comply with the animal health requirements of Chapter 1 of the said Directive, applicable to all stages of the production, processing and distribution of such products in the Union, or offer equivalent animal health guarantees thereto.

Article 8 of Directive 2002/99/EC provides for the establishment of lists of third countries or regions of third countries from which imports of specified products of animal origin are permitted and requires the Commission to take particular account, amongst other things, of:

- the actual animal health requirements applying to the production, manufacture, handling, storage and dispatch of products of animal origin intended for the EU;
- the health status of livestock, other domestic animals and wildlife in the third country, with particular regard to exotic animal diseases and any aspects of the general health situation in the country which might pose a risk to public or animal health in the EU; and
- the rules on the prevention and control of infectious or contagious animal diseases in force in the third country and their implementation, including rules on imports from other countries;
- the regularity, speed and accuracy with which the third country supplies information on the existence of infectious or contagious animal diseases in its territory, particularly the notifiable diseases listed by the OIE.

Article 5 of Regulation (EC) No 798/2008 sets out animal health conditions to be complied with by commodities imported into the EU. Specific conditions laid down in Chapter III to the said Regulation concerning the animal health status of third countries, territories, zones or compartments with regard to AI and ND, require that they shall be considered as free from these diseases as defined in Articles 9 and 12, respectively, therein.

Articles 10.4.2 and 10.13.2 of the Terrestrial Code define, respectively, the criteria to be followed for determination of the health status with regard to AI and ND of a country, zone or compartment. One of these criteria is that appropriate surveillance is in place to demonstrate the presence of infection with AI virus and ND virus in the absence of clinical signs in poultry, and in the case of AI virus, the risk posed by birds other than poultry:

- A country, zone or compartment may be considered free from AI when it has been shown that neither HPAI nor LPAI infection in poultry has been present in the country, zone or compartment for the past 12 months, based on surveillance in accordance with Articles

10.4.28 to 10.4.34 of the Terrestrial Code.

- A country, zone or compartment may be considered free from ND when it has been shown that no ND virus infection in poultry has been present in the country, zone or compartment for the past 12 months, based on surveillance in accordance with Articles 10.13.22 to 10.13.26 of the Terrestrial Code.

5.3.2 Findings

5.3.2.1 General animal health controls

The FVO team found that:

- Approval of commercial farms requires conditions that facilitate prevention and control of infectious diseases. Compulsory bio-security measures in this sector theoretically reinforce the trust in the control of the health situation of this compartment, as they were seen to be, in most cases, properly supervised. Some minor doubts remain though as reports of official controls frequently underlined insufficient compliance with issues such as disinfection arrangements (e.g. disinfectant mats) or handling and disposal of poultry manure. These non-compliances have though not been addressed properly in most of those cases.
- In the commercial poultry sector, the control of animal health requirements is the responsibility of official veterinarians (OV) from the local veterinary stations (LVS) of the DVOs who are responsible for daily supervision of the farms. Production and mortality data are collected daily and there was evidence that these data are analysed systematically, and mostly effectively, for the early detection of infectious diseases. These activities are also supervised by staff of the DVOs.
- Vaccination of commercial poultry and backyard poultry against ND is obligatory, except for ducks and geese. Accordingly, holdings with backyard poultry are registered, vaccinated and controlled by OV from the LVS. Vaccination, monitoring of levels of herd immunity and re-vaccination as appropriate, take place regularly in both commercial farms and back yard flocks, as programmed by the CA.
- The characteristics of the ND vaccines registered in Ukraine are, in principle, in accordance with the requirements of EU legislation, as according to representatives of the CA, only lentogenic master seed strains with an intra-cerebral pathogenicity index of maximum 0.2 can be used. Some of these strains (well-known internationally) have been on a restricted list incorporated in an Order since 2004. Additional strains are now included in newly licensed vaccines even if their incorporation in the prior list is still in draft format (see weaknesses in legislation above).

5.3.2.2 Import controls

The policy on import requirements includes the listing of countries not allowed to export commodities to Ukraine on the basis of the most updated OIE notifications on outbreaks of AI and ND; in addition, the CA carry out on-the-spot animal health assessments for some third countries so that they can verify the possible presence of potential animal health risks related to the potential imports. Some points to be underlined in this respect are:

- In general, import certificates require CA of exporting countries to certify freedom from HPAI and from ND for six months if a stamping out policy is applied (stricter than OIE and EU requirements, three months); however, there is no additional requirement on the type of disease surveillance that those countries must have done to substantiate the regained free-status for these diseases, as laid down in the Terrestrial Code (Articles 10.4.4 and 10.13.3,

respectively) and in Articles 9 and 12 of Regulation (EC) No 798/2008;

- In the case of imports from members of the Commonwealth of Independent States, such as the Russian Federation, Belarus or Kazakhstan, no specific attestation is required in relation to AI or ND but only a general statement on the favourable animal health status of the country of origin;
- In most cases, there is no certification requirement on vaccination against AI or ND, and there is no legal requirement on the type of vaccines against ND that can be used by exporting countries; and
- Some countries from which commodities are imported into Ukraine are not on the EU list of authorised countries laid down in Regulation (EC) No 798/2008 for those commodities; e.g. imports of day-old chicks are authorised from countries such as the Russian Federation, Belarus, Turkey, Serbia or Kazakhstan.

An extensive network of border inspection points is responsible for carrying out import controls on poultry commodities; arrangements in this respect appear to be satisfactory and the operation of the system can be considered equivalent to EU standards.

Specific arrangements are in place for imported day-old chicks with respect to quarantine; at the farms visited there were provisions to ensure proper isolation and extensive animal health checks and sampling to exclude the introduction of AI or ND.

5.3.2.3 Animal health status with regard to AI and ND

Numerous initiatives have been introduced since 2006 in order to raise the awareness of all stakeholders with respect to the importance of identifying and notifying any suspicion of HPAI; this was further intensified after the outbreaks in the Crimean peninsula in 2008 and more recent outbreaks in neighbouring countries such as Romania or the Russian Federation.

- The FVO team noted a high level of awareness in commercial farms; however, there has not been any suspicion of the disease for some years in either the former or in backyard flocks.
- The presence of a contingency plan (CP) for AI and the annual simulation exercises organised by the DVOs have contributed to enhance the level of preparation for actions to be implemented in case of suspicion or confirmation. Similar arrangements are in place concerning ND, but they have not been laid down in the form of a CP; nonetheless, according to the CA, the practice obtained with the regular simulation exercises for AI would facilitate an early and effective response in the event of an outbreak of this disease. They added that minor outbreaks of ND detected in 2006 and 2007 had been effectively managed thanks to, amongst other things, the above mentioned experience derived from AI simulation exercises.

A sampling programme for active surveillance of AI has been drawn up for the last years including commercial farms, poultry in backyard flocks and wild and synanthropic bird populations. According to the CA, the number of samples to be taken annually, their geographical distribution and the bird species targeted are based on the size of the commercial population and on the risk associated with the location or type of the farm as associated to possible risks of spread of AI from migratory wild birds.

- The FVO team found that, in reality, the theoretical risk-based surveillance was applied only partially and that distribution of the sampling effort was spread almost evenly throughout the country taking into account the number of commercial farms and settlements with backyard flocks instead of targeting areas where a high risk of infection, as assessed by the SCVMU, could be present.

- Sampling sizes were adequate to detect possible circulation of AI virus in commercial farms but mostly insufficient to guarantee a comparable sensitivity in backyard flocks. For the latter, examples checked of sampling carried out in settlements showed that it was very difficult to verify how a risk-based approach had been followed as, for instance, hardly any samples are taken from species where a higher risk of inapparent infection with the AI virus, such as dusks and geese, is likely to occur. Moreover, some of the OV met were not sufficiently aware of the risk factors they had to bear in mind when selecting animals for sampling.
- Sampling points determined for wild birds were based on their migratory routes and resting or nesting areas. A targeted sampling plan is implemented annually but the available results, with nearly no detection for several years (only two birds with a LPAI strain that were found in 2009), suggest that the reliability of the detection by the laboratory of possible strains of AI circulating therein, i.e. LPAI, could be lower than necessary (see weaknesses pointed out in the chapter on the laboratories).
- The last outbreaks of ND occurred in 2007. They were very restricted geographically and had only involved small backyard flocks; no other case of the disease had been detected since. As compulsory vaccination is applied, no specific sero-surveillance is in place for ND, but rather the sero-monitoring of vaccination coverage. According to representatives of the CA, passive surveillance for ND is guaranteed in commercial farms as any clinical incident is investigated bearing in mind the possible incursion of an exotic disease (see 5.3.2.1); however, the same does not apply to backyard flocks where no targeting is applied to species that may not show clinical signs of ND and are not routinely vaccinated (e.g. ducks).

5.3.3 Conclusions

Import risk management measures currently in place for poultry commodities are not fully in compliance with standards laid down in the Terrestrial Code and can not be considered fully equivalent to EU provisions, in particular owing to the absence of import requirements for: a) any disease surveillance needed to substantiate free status for HPAI and ND; b) vaccination status of poultry against AI and ND; and c) type of ND vaccines authorised in the exporting countries.

The AI and ND surveillance programmes in place that aim to demonstrate the absence of infection with AI and ND viruses are largely applied in accordance with standards laid down in Chapters 10.4 and 10.13 of the Terrestrial Code. However, some weaknesses in that respect have been found, such as:

- implementation of the current surveillance for AI in backyard flocks can not be considered strictly risk-based as claimed by the CA;
- limited reliability of the negative results obtained from samples taken from wild birds; and
- a surveillance programme for ND that is not sensitive enough to detect the presence of circulating strains of the virus other than the ones used in the registered vaccines.

Those weaknesses cast some doubts on the robustness of the surveillance data obtained and the validity of their use to substantiate claims for freedom of the diseases.

5.4 International veterinary certification

5.4.1 Legal requirements

Council Directive 96/93/EC and Annex IV to Directive 2002/99/EC describe the general principles for international veterinary certification.

Part II of Annex I to Regulation (EC) No 798/2008 contains the models of health certificates that lay down the animal and public health veterinary certification requirements for the importation into the Union of poultry meat, eggs and eggs products. Moreover, amongst the general notes lay down in this regard, the said Regulation requires that the original of the certificate must be completed and signed by an OV and that the CA of the exporting country shall ensure that the principles of certification equivalent to those laid down in Directive 96/93/EC are followed.

Annex III to Decision 2007/777/EC contains the models of health certificates that lay down the animal and public health veterinary certification requirements for the importation into the Union of poultry meat products.

5.4.2 Findings

The certification system to be used for the possible export of poultry commodities to the EU could be partially verified in practice, as current arrangements for internal movement and certification of live poultry, hatching eggs and poultry products will not differ much from additional arrangements that could be introduced once Ukraine is authorised to export to the EU. The current chain of certification should largely allow for the specific health attestations included in the veterinary certificates for the relevant commodities to be based on reliable and accurate animal health information.

5.4.3 Conclusions

The CA of the Ukraine can largely ensure that principles of certification equivalent to those laid down in Directive 96/93/EC will be followed when the health certificates required by Regulation (EC) No 798/2008 and Decision 2007/777/EC will have to be issued to accompany poultry commodities to be exported to the EU.

6 Overall Conclusions

A sufficiently empowered and well resourced CA is able to carry out effective animal health controls on the poultry population in Ukraine and can largely ensure detection and adequate management of an outbreak of HPAI. Besides that, the vaccination policy against ND can be considered equivalent to EU provisions in that respect. Therefore, in general, the CA are in a position to offer the animal health guarantees required for certifying poultry meat, eggs and their products to be exported to the EU, in particular because of the limited number of fully integrated companies that are envisaged to avail of this possibility.

Nonetheless, some shortcomings have been identified that undermine the capability of the system in place to manage certain risks to the general animal health situation of the poultry population in Ukraine. These concern in particular:

- Legal requirements in place on the definitions of AI and ND, as well as on the distinction between low pathogenic avian influenza (LPAI) and HPAI, that can not be considered fully in accordance with EU provisions and international standards laid down by the World Organisation for Animal Health (hereafter, OIE) in the Terrestrial Animal Health Code

(hereafter referred to as the Terrestrial Code);

- Import risk management measures for poultry commodities that are not totally in compliance with standards laid down in the Terrestrial Code and that can not be considered fully equivalent to EU provisions;
- Virological and serological diagnostic systems for AI and ND that are not effective enough to guarantee confirmation of outbreaks of these diseases without unnecessary delay and to unequivocally exclude the possible circulation of strains of LPAI and field strains of ND; and
- Implementation of the sero-surveillance programme for AI in backyard flocks and wild birds that can not be considered sensitive enough to detect low or inapparent incidence of the disease in those bird populations.

7 Closing Meeting

A closing meeting was held on 10 December 2010 with representatives of the CCA during which the FVO team presented the main findings and preliminary conclusions of the inspection. The CCA did not disagree with them, undertook to take immediate action to address the shortcomings identified by the FVO team and already offered evidence in that respect during the course of the meeting.

8 Recommendations

The CCA of Ukraine is invited to submit an action plan describing the actions taken or planned in response to the recommendations of the report and setting out a timetable for their completion. This information should be presented to the Commission within 25 working days of receipt of this report.

N°.	Recommendation
1.	To incorporate additional legal requirements on the definitions of AI and ND, as well as on the distinction between LPAI and HPAI, in order to bring them fully in accordance with EU provisions laid down in Regulation (EC) No 798/2008 and international standards laid down by the OIE in chapters 10.4 and 10.13 of the Terrestrial Code.
2.	To enhance the reliability of the serological and virological diagnostic systems for AI and ND by abiding by diagnostic standards laid down in chapters 2.3.4 and 2.3.14 of the Terrestrial Manual, so that earlier detection of outbreaks can be guaranteed and possible circulation of strains of LPAI and field strains of ND, can be excluded.
3.	To reinforce the import risk management measures for poultry commodities, so that they are in compliance with standards laid down in the Terrestrial Code and can be considered equivalent to EU provisions laid down in Regulation (EC) No 798/2008 and Decision 2007/777/EC.
4.	To reconsider the current implementation of surveillance for AI and ND in backyard flocks and wild birds in order to better substantiate and reliably certify the animal

N°.	Recommendation
	health status of the poultry flock in Ukraine as free from AI and ND in accordance with definitions in that respect laid down in Articles 10.4.2 and 10.13.2 of the Terrestrial Code, and in Articles 9 and 12 of Regulation (EC) No 798/2008.

The competent authority's response to the recommendations can be found at:

http://ec.europa.eu/food/fvo/ap/ap_ua_2010-8808.pdf

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Dir. 2002/99/EC	OJ L 18, 23.1.2003, p. 11-20	Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption
Reg. 798/2008	OJ L 226, 23.8.2008, p. 1-94	Commission Regulation (EC) No 798/2008 of 8 August 2008 laying down a list of third countries, territories, zones or compartments from which poultry and poultry products may be imported into and transit through the Community and the veterinary certification requirements
Dec. 2007/777/EC	OJ L 312, 30.11.2007, p. 49-67	2007/777/EC: Commission Decision of 29 November 2007 laying down the animal and public health conditions and model certificates for imports of certain meat products and treated stomachs, bladders and intestines for human consumption from third countries and repealing Decision 2005/432/EC
Dir. 2005/94/EC	OJ L 10, 14.1.2006, p. 16-65	Council Directive 2005/94/EC of 20 December 2005 on Community measures for the control of avian influenza and repealing Directive 92/40/EEC
Dir. 92/66/EEC	OJ L 260, 5.9.1992, p. 1-20	Council Directive 92/66/EEC of 14 July 1992 introducing Community measures for the control of Newcastle disease
Dec. 2006/437/EC	OJ L 237, 31.8.2006, p. 1-27	2006/437/EC: Commission Decision of 4 August 2006 approving a Diagnostic Manual for avian influenza as provided for in Council Directive 2005/94/EC
Dir. 96/93/EC	OJ L 13, 16.1.1997, p.	Council Directive 96/93/EC of 17 December 1996

Legal Reference	Official Journal	Title
	28-30	on the certification of animals and animal products